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EXAMINER

HOPKINS, CHRISTINE D

ART UNIT	PAPER NUMBER
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3735

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/803,773

Applicant(s)

WEINBERGER, JUDAH Z.

Examiner

Christine Hopkins

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-11 and 22-29 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-4, 6-11 and 22-29 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed March 6, 2006. Claims 1-4, 6-11, and 22-29 are now pending. The Examiner acknowledges the amendments to claims 1, 8, 22, 25 and 28.

Claim Objections

2. Claims 1 and 8 are objected to because of the following informalities: at line 4 of claim 1, a comma should follow "process." At line 17 of claim 18, "outersurface" should be deleted. At line 6 of claim 28, "expandible" should read --expandable--.Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 positively recites a tube segment that has radioactive material "substantially uniformly disbursed throughout its structure." Whereas the

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original disclosure fails to teach such a feature, only claims 8 and 22 were amended to obviate the rejection under 35 USC 112, first paragraph, as set forth in the Office Action mailed 30 November 2005.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At claim 22, line 17, the pronoun "its" renders the claim indefinite because one cannot be certain whether it refers to the luminal structure or the tube segment.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 3, 8, 7, 10 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Klein ('284). Klein teaches an apparatus for radiation treatment of an

internal body lumen. The apparatus includes a balloon catheter **34** having an inflatable balloon **32** and a tube segment. The tube segment is defined as the radiation-emitting terminal portion of catheter **10**, which is consistent with the disclosure of the instant application at page 9, lines 1-4. The entire tube segment is adapted to be longitudinally slid over, carried by and cover the balloon. The radiation-emitting tube segment is substantially the same length as the balloon (see at least Figures 5-8). The tube segment includes a radioactive material **30,302** that is mixed with a non-radioactive material **38** (col. 24, lines 65-67). The radioactive material is uniformly disbursed around its entire circumferential extent throughout the structure of the tube segment formed by the radiation-emitting terminal portion of catheter **10**, and particularly when considered longitudinally. The tube segment can be an expandable and collapsible material (col. 5, lines 6-18), such that the tube segment is expandable in a range of sizes and the entire shape of the tube segment is determined by the shape of the balloon as the balloon inflates to expand the segment and deflates to collapse the segment. Embodiments of the tube segment are formed of an elastomeric material that covers the balloon substantially entirely during inflation (col. 12, lines 35-39 and Figs. 5-6). The outer surface of the tube segment is exposed to come into direct contact with the luminal structure. In operation, the balloon catheter **34** is inserted into the body lumen; the radioactive tube segment at the terminal portion of catheter **10** is longitudinally slid over the balloon catheter **34** such that the tube segment including the radioactive material **30,302** is disposed over the balloon **32**; the balloon **32** is inflated with fluid to expand the tube segment and administer a radiation dose to the luminal

structure; the balloon **32** is deflated and the tube segment collapsed; and the balloon catheter **34** and tube segment are removed from the luminal structure.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 2 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein ('284) in view of Hess ('168). Klein teaches all of the limitations of the claims except that the radioactive material is in the form of a coating on the tube segment. It is well known in the art that a non-radioactive material can be provided with radioactive characteristics by coating the non-radioactive material with a radioactive material. Hess teaches a stent **74** which is coated with a radioactive material in order to assist in preventing restenosis of an artery. It would have been an obvious engineering design choice to one skilled in the art at the time the invention was made to make a radioactive tubular segment similar that of Klein by coating a tubular segment with a radioactive material in view of the teachings of Hess in order to produce a tube that is radioactive at its distal end.

11. Claims 4 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein ('284) in view of Lewis et al. ('552). Klein teaches all of the limitations of the claims except that the tube segment includes a non-radioactive material into which is

absorbed radioactive material. Lewis et al. teach that it is known in the art to make intra-luminal radiation devices of a non-radioactive material into which is absorbed radioactive material. It would have been an obvious engineering design choice to one skilled in the art at the time the invention was made to make a radioactive tubular segment similar that of Klein by absorbing radioactive material into a non-radioactive material in view of the teachings of Lewis et al. in order to produce a tube that is radioactive at its distal end.

12. Claims 6, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein ('284) in view of Fischell et al. ('282). Klein teaches all of the limitations of the claims except that the tube segment is adhesively attached to the balloon and that the balloon is inflated with a gas. Fischell et al. teach a catheter having an expandable radioactive source. The catheter includes a balloon **14** with an expandable, elastic radioactive tube segment **16** adhesively attached to the balloon **14** by an outer balloon **15** which is heat sealed (shrunk) to the inner balloon (col. 5, lines 2-6). The balloon **14** is inflated with a carbon dioxide gas to bring the tube segment into proximity to a luminal structure (col. 6, lines 51-53). It would have been obvious to one having ordinary skill in the art that since the radioactive source **16** is expandable and elastic, the dosage per surface area of the source would inherently be different in an inflated state than that of the unexpanded state. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to adhesively attach the tube segment to the balloon of a radiation treatment device similar to that of Klein in view of the teachings of Fischell et al. in order to ensure proper positioning of the expandable radioactive tube

segment with respect to the balloon. It further would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use a carbon dioxide gas as an inflation medium in view of the teachings of Fischell et al. in order to inflate the balloon catheter of a device similar to that of Klein as an obvious engineering design choice, merely substituting one known inflation medium for another that is capable of performing the same function.

13. Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roubin et al. ('257) in view of Klein ('284). Roubin et al. teach a minimally invasive medical device for providing radiation treatment in the vicinity of a luminal structure (see Figure 5). The tube segment **59** includes radioactive material **63** for producing radiation for treating a disease process. The tube segment has varying concentrations of radioactive material for producing a radiation dose that varies at least axially and longitudinally along the tube segment. The tube segment **59** has substantially equal wall thickness along its longitudinal length (see Figure 5). However, Roubin does not disclose a tube segment being made of expandible and collapsible material. Klein teaches an apparatus for radiation treatment of an internal body lumen. With respect to claim 25, the device of Klein contains a tube segment or sleeve **10** which is expandible and collapsible based on the elastomeric properties of the material from which it is produced (col. 5, lines 6-18). Furthermore, the expandible and collapsible nature of the Klein device allows the device to be transported in a low profile configuration and subsequently expanded to provide treatment of a desired location. Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's

invention was made to incorporate the expandible and collapsible material of Klein to the tube segment of Roubin for surgical techniques which involve invasively delivering radioactive material through a body passageway.

14. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roubin et al. ('257) in view of Pflueger ('038) and further in view of Klein ('284). Roubin et al. teach a minimally invasive medical device for providing radiation treatment in the vicinity of a luminal structure (see Figure 5). However, Roubin does not disclose a tube segment being made of expandible and collapsible material. Klein teaches an apparatus for radiation treatment of an internal body lumen made of an expandible and collapsible material; see rejection supra. Pflueger teaches that a balloon catheter **12** including a shaft and an inflatable balloon **30** may be inserted maneuvered through the lumen of a tubular catheter in order to secure the positioning of the catheter within the body. However, Pflueger does not disclose a tube segment having material for producing a radiation pattern. Klein teaches an apparatus for radiation treatment of an internal body lumen having a tube segment or sleeve **10** for producing a radiation dose that varies at least longitudinally and axially, and is expandible and collapsible based on the elastomeric properties of the material from which it is produced (col. 5, lines 6-18). It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use a balloon catheter similar to that of Pflueger as the guidewire, in a tube segment similar to that of Roubin et al., and comprising the expandible and collapsible material of Klein, in order to anchor the tube segment at a

desired treatment position and provide a material which can adapt to the conformation of passageways within the body.

Response to Arguments

15. Applicant's arguments filed March 6, 2006 with regard to claim rejections under 35 USC 112, first paragraph, have been fully considered and are not persuasive. The language of claim 1 positively recites "substantially uniformly disbursed throughout its structure." Applicant states that this limitation was deleted from claim 1; however, no such amendment has been made. Further regarding claim 1, Applicant contends that claims 1, 8 and 22 have been amended to recite a polymer; however, no such amendment was made.

16. Applicant's arguments filed March 6, 2006 with regard to claim rejections under 35 USC 112, second paragraph, have been fully considered and are persuasive. The rejection of claims 1-4, 6 and 7 under 35 USC 112, second paragraph, has been withdrawn.

17. Applicant's arguments filed March 6, 2006 with regard to the claim rejections under 35 USC 102(e) citing Klein have been fully considered but are not persuasive. Applicant contends that the Klein reference does not disclose "providing a radiation pattern which is uniform around its entire circumferential extent." However, this argument is not persuasive. Klein discloses a separate embodiment exemplifying a

uniform radiation pattern around its entire circumference as depicted in Figs. 19 and 20A. The invention incorporates a guidewire **114** and a secondary radiation source **115** positioned within the lumen of the balloon catheter to provide circumferential radiation dose distribution at a vessel wall (col. 17, lines 26-37). Thus, the Examiner contends that not only does Klein substantially disclose this teaching, but the tube segment of Klein is arranged in such a way that the angle of emission of the radioactive material achieves "a uniform radiation distribution around its entire circumferential extent."

These arguments remain not persuasive.

18. Applicant's arguments filed March 6, 2006 with respect to the rejection of claim 25 under US 102(b) citing Roubin et al. ('257) have been fully considered but are moot in view of the new grounds of the rejection set forth above, citing Roubin et al. in view of Klein ('284).

19. Applicant's arguments filed March 6, 2006 with respect to the rejection of claim 28 over Roubin et al. ('257) in view of Pflueger ('038) have been fully considered but are moot in view of the new grounds of the rejection set forth above, citing Roubin et al. ('257) in view of Pflueger ('038) and further in view of Klein ('284).

Conclusion

20. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on M-F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles A. Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

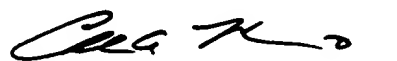
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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christine Hopkins
Examiner
Art Unit 3735



Charles A. Manner, II
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